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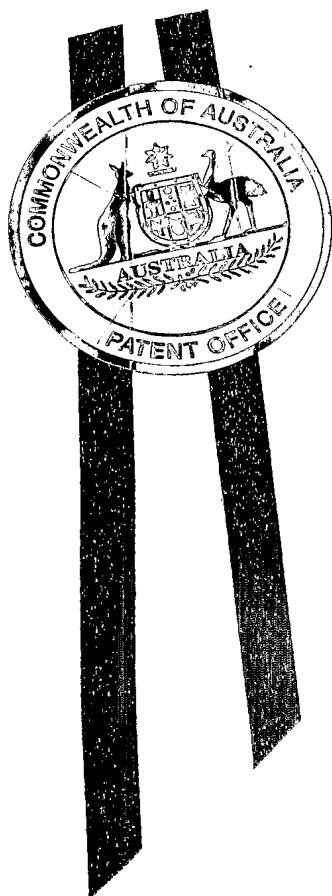


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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003907169 for a patent by AYZALA PTY LTD as filed on 31 December 2003.



WITNESS my hand this
Eighteenth day of January 2005

A handwritten signature in black ink, appearing to be 'LA'.

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT
AND SALES

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Regulation 3.2

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title: "A METHOD OF PRIORITISING A
SAMPLE"

The invention is described in the following statement:

TITLE

"A METHOD OF PRIORITISING A SAMPLE"

FIELD OF THE INVENTION

This invention relates to a method of prioritising a sample. In particular, the invention relates to prioritising the testing of a biological sample obtained from a patient and therefore will be described in this context. However, it should be appreciated that the method may also be used to prioritise other samples such as those obtained from animals.

BACKGROUND OF THE INVENTION

Specimen containers are used to collect and process biological samples, such as blood, urine, faeces, infected material, tissue etc from patients for testing purposes. It should be appreciated that the term "specimen container" may include any form of container including tubes, buckets, cups or the like containers.

The specimen containers have a label located on the specimen container that is applied during production of the specimen container so that details of the patient can be recorded. Once the biological samples are collected, they are then usually tested in a pathology laboratory to determine if the patient is unwell or suffering from a disease. Other samples may undergo different types of laboratory testing including cultivation and/or culture.

The normal process in obtaining a test result for a patient involves:

1. An experienced practitioner determining what test is necessary;

2. Collecting a sample using a specific specimen container based on the desired test;
3. Recording the details of the person from whom the sample was collected and on whom the test is to be conducted on a label located on the specimen container;
4. Filling-in paperwork outlining the details of the test to be completed;
5. Sending the specimen container and associated paperwork to the pathology laboratory;
6. The pathology laboratory receiving the specimen container and paperwork;
7. The pathology laboratory conducting the tests outlined in the paperwork; and
8. Forwarding the results to the practitioner.

In many instances, it is necessary that the tests be conducted in an urgent or prioritised manner. In order that the tests are prioritised by the pathology laboratory, the practitioner normally indicates this urgency on the paperwork that accompanies the specimen container.

To indicate that the test on the biological sample is urgent, many pathology laboratories use indicators that are placed on the specimen containers. These indicators are normally in the form of coloured stickers or markings that are located on the container. The stickers or markings are in various forms such as dots or stripes. Though these stickers or markings are effective, they are time consuming to apply and normally have to be specially

manufactured to suit the specific containers.

There are frequent occasions when a prioritised test is not conducted on a biological sample within the time frame that it is required.

This is normally due to the pathology laboratory overlooking the urgency

5 indication on the paperwork or occasionally due to the paperwork not signifying that the test is urgent. It may also be due to the sticker being removed from the specimen container.

This can be life threatening when tests are required to diagnose potentially fatal illnesses. It can also lead to significant delays in

10 major public health scenarios such as disease outbreaks.

OBJECT OF THE INVENTION

It is an object of the invention to overcome or alleviate one or more of the above disadvantages or provide the consumer with a useful or commercial choice.

SUMMARY OF THE INVENTION

15

In one form, although not necessarily the only or broadest form, the invention resides in a method of prioritising a sample, the method comprising the steps of:

incorporating a prioritising indicator into a specimen container

20

wherein the indicator is incorporated into the specimen container prior to a sample being located within the specimen container.

Preferably, the indicator is incorporated into the specimen container during production of the specimen container.

The indicator may be incorporated into a lid and/or body of the

specimen container. Preferably, the indicator is located on the body adjacent an opening of the specimen container.

The indicator may extend around the lid and/or body of the specimen container.

5 The indicator may form part of a label that is applied to the specimen container. Alternatively, the indicator may be integral with the specimen container. Still alternatively, the indicator may be printed onto the specimen container.

10 The indicator may include words to indicate the priority and/or level of prioritisation of the sample and may include a grading system. Alternatively, different coloured indicators and/or different styles of indicators may be used to inform different levels or gradings of prioritisation

Preferably, the indicator is brightly coloured and/or sized so that it is visible from a distance.

15 In another form, the invention resides in a label for a specimen container, the label comprising:

a details section to allow for the recordal of the details of a patient on the specimen container; and

20 an indicator band for indicating a priority for the specimen container, the band joined to the details section;

wherein the band is wider than the details section.

The indicator band may include words to indicate the priority and/or level of prioritisation of the sample and may include a grading system. Alternatively, different coloured indicators and/or different styles of indicators

may be used to inform different levels or gradings of prioritisation.

The details section may include a location for the surname, first name, date of birth, time, signature, ward, patient number or similar details.

5 The details section may also include a fill line, that when applied to a body of the specimen container, indicates the level of fluid that the body is to be filled to.

The details section may also include a location for the sample type.

10 The details section may also include a batch number and/or expiry details and/or date of manufacture of the container.

The details section may also include a biohazard and/or radiation marker or symbol and/or some other hazard or warning symbol

15 The details section may also include a human readable and bar code specifying a laboratory or sample number that may also have a removable and adherent portion of the same human readable and bar code number.

The details section may also include a human readable and bar code specifying the urgency of the sample/specimen.

20 Preferably, the indicator band is brightly coloured and/or sized so that it is visible from a distance.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Embodiments of the invention, by way of examples only, will be described with reference to the accompanying drawings in which:

FIGS. 1A to 1E show different embodiments of prioritising

indicators that have been applied to a specimen container;

FIG. 2A shows the label, in detail, that has been applied to the specimen container of FIG. 1E; and

FIG. 2B shows a further embodiment of the label of FIG. 1E;

5 FIG. 2C shows yet another further embodiment of the label of
FIG 1E

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

FIGS 1A to 1E show specimen containers 10 that are typically used for the collection of blood. Each specimen container has a lid 11 and a
10 body 12. The body 12 contains the blood sample whilst the lid 11 is removable from the container and seals an opening contained within the body 12 through which the blood enters the body 12.

Each specimen container 10 also has a label 13 located on the container. The label 13 is a sticker that is applied to the specimen container
15 during manufacture i.e., in production. The label 13 is sized so that it only extends partially around the body 12 so that a view window is left on the container to view the level of blood within the body 12.

The label 13 has a details section that includes discrete labelled zones for surname, first name, date of birth, time that the sample
20 was taken, signature of the person who took the same, the ward number, and patient number. However, it should be appreciated that the details label may be varied according to specific requirements.

The label also includes a fill line that indicates the level of fluid that the body is to be filled to. The fill line must be precisely located with

respect to the body and hence a major reason why the label is applied to the body during manufacture.

FIG. 1A shows the specimen container with a label 13. A prioritising indicator 14 is located above this label on the body 12 of the specimen container 10. In this embodiment, the prioritising indicator 14 is in the form of band that extends the circumference of the body. The band is fluorescent and hence can be readily identified by a person.

FIG. 1B shows a very similar prioritising indicator 14 to that shown in FIG. 1A. In this embodiment, the prioritising indicator 14 is printed onto the body 12 and is in the form of a dotted band that extends around the circumference of the body 12.

FIG. 1C shows a prioritising indicator 14 located on the lid 11 of the specimen container 10. The indicator 14 is in the form of a band of dots that extend around the circumference of the lid 11.

FIG. 1D shows a prioritising indicator 14 located on the lid 11 and the body 12 of the container 10. The prioritising indicator is in the form of two bands of triangles that extend around the lid 11 and the body 12 of the container 10.

FIG. 1E shows a prioritising indicator 14 that is integrally formed with the label. The label includes a details section and the prioritising indicator in the form of an indicator band 14

FIG. 2A shows the label prior to it being placed on the body of the specimen container. As can be seen, the details section 16 carries the standard elements of a standard label as described above.

The indicator band 14 is substantially wider than the details section. The indicator band extends entirely around the body whilst the details section 16 only extends partially around the body 12. This allows a window to view the sample as outlined above.

5 In this embodiment, the details section 16 is located adjacent one end of the indicator band 14.

FIG. 2B shows that the details section 16 can be located in the adjacent middle of the indicator band.

10 FIG. 2C shows the details section with some modifications such as the name and colour code of the anticoagulant/preservative, batch number and expiry date.

It should be appreciated that by incorporating the prioritising indicator into the specimen container during production, this will automate the process making the container for urgent samples cheaper to produce.

15 Further, existing machinery, such as the label applicators, can be simply modified to place the label with the integrated indicator band onto the body of the container.

Further, the utilisation of specimen containers with incorporated prioritisation indicators will, by easy visual identification of urgent samples

20 from a distance to all people handling the specimen containers, assist in expediting the testing process from sample collection through sample transportation, sample receipt in the laboratory, laboratory testing, result validation/verification, report production and sample storage through to sample disposal.

Further, the utilisation of specimen containers with incorporated prioritisation indicators will eliminate the risk of failure to recognize a high priority sample and/or the separately applied priority indicator becoming dislodged or removed.

- 5 Further, the utilisation of specimen containers with incorporated prioritisation indicators will expedite the testing process when no accompanying paperwork has been received or if requested tests are ordered electronically.

- 10 It should also be appreciated that various other changes and modifications may be made without departing from the spirit or scope of the invention.

DATED this-

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by its Patent Attorneys

FISHER ADAMS KELLY

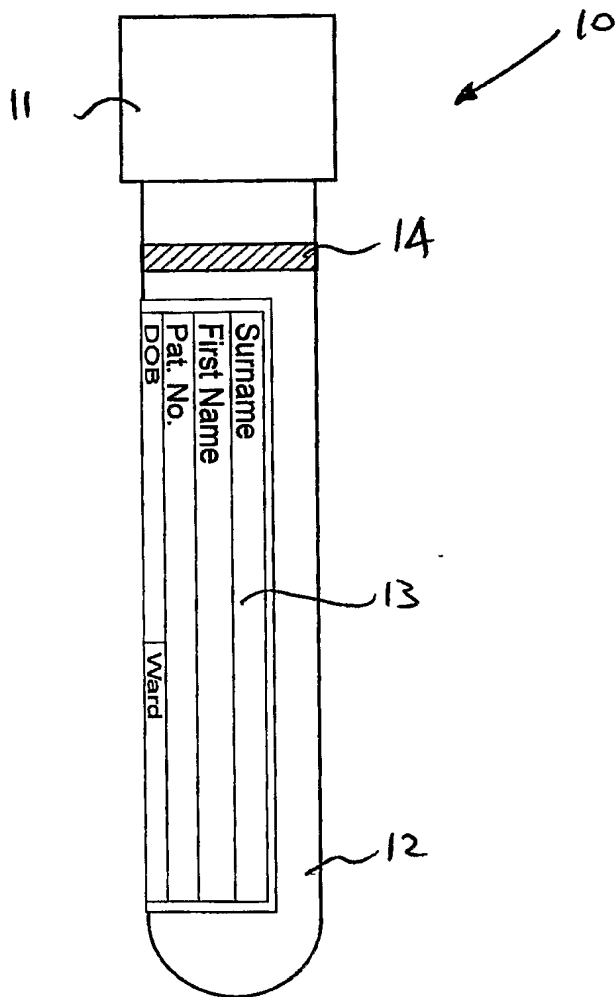


FIG. 1A

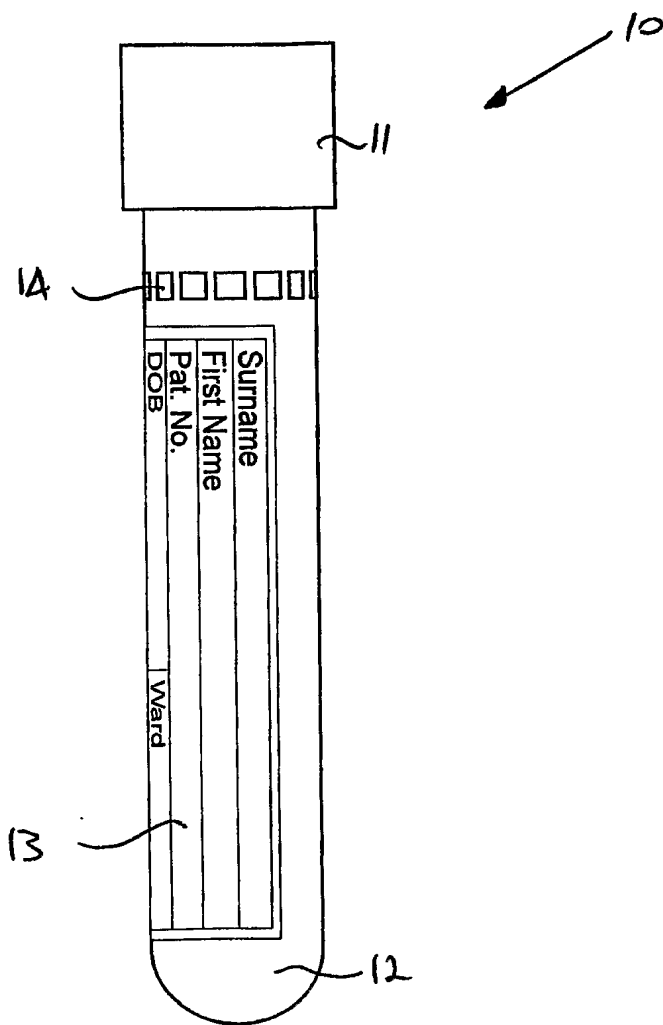


FIG. 1B

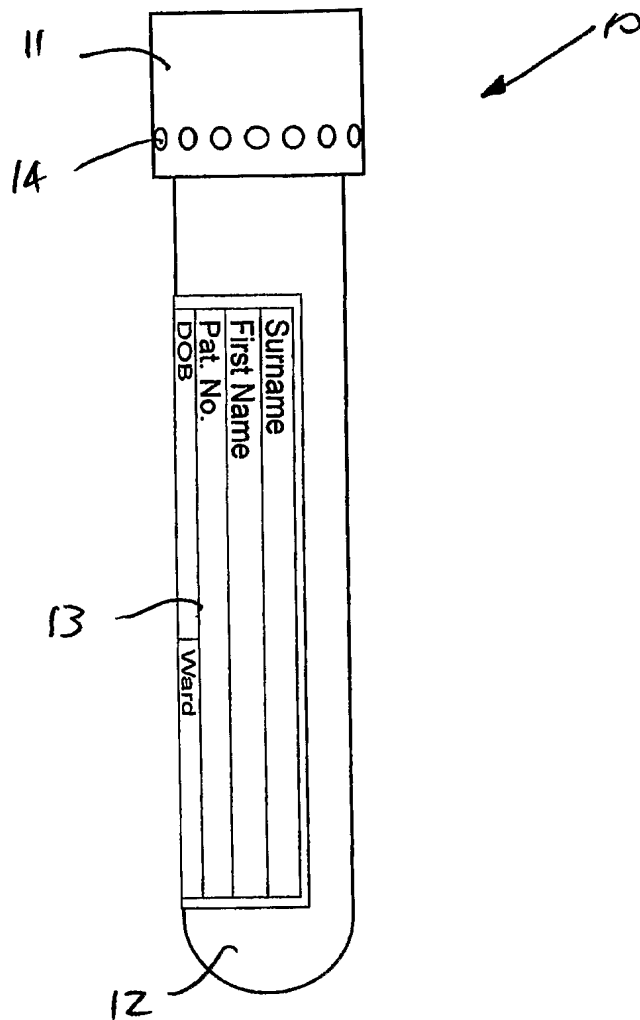


FIG. 1C

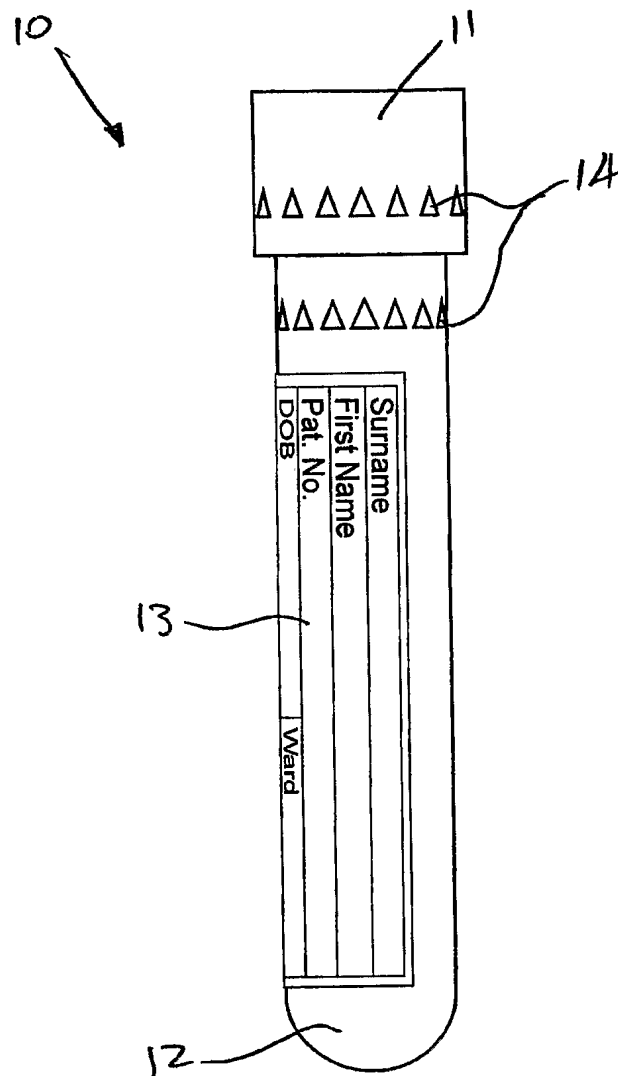


FIG. 1D

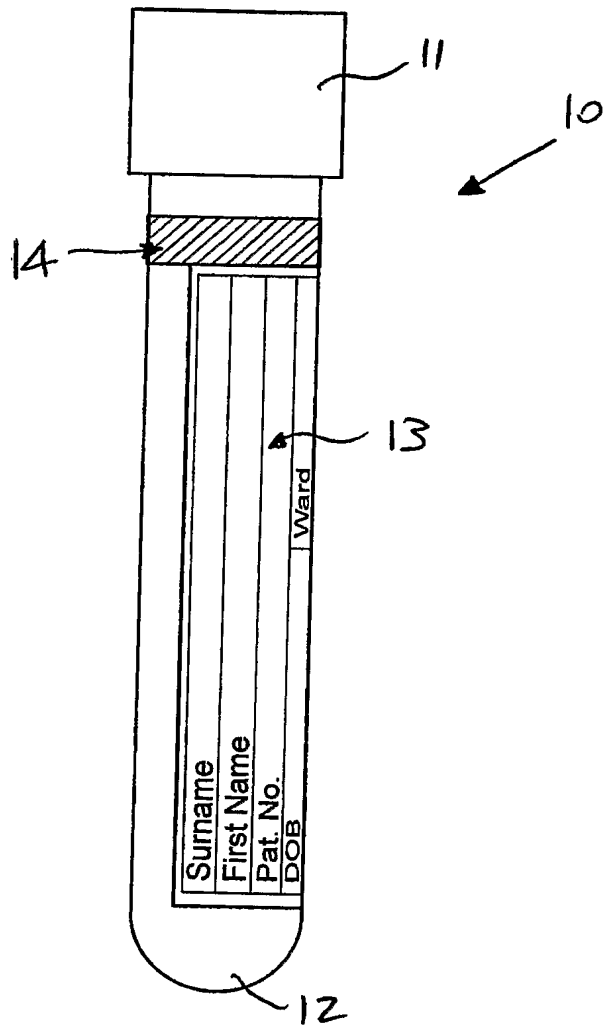


FIG. 1E

13

14

16

URGENT URGENT URGENT

| | |
|--------------------|------------------------|
| Patient Name | Date of Birth |
| Patient Number | Signature of Collector |
| Date of Collection | Time of Collection |
| Ward/Clinic | Doctor |

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FIG 2A

13

14

16

STAT STAT STAT STAT

| | |
|--------------------|------------------------|
| Patient Name | Date of Birth |
| Patient Number | Signature of Collector |
| Date of Collection | Time of Collection |
| Ward/Clinic | Doctor |

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FIG 2B

| | | |
|--|---------------------|------------------------|
| | Patient Name | Date of Birth |
| | Patient Number | Signature of Collector |
| | Date of Collection | Time of Collection |
| | Ward/Clinic | Doctor |
| | Batch Number 123456 | Expiry Date 03/06 |

FIG 2C